K082410

510(k) Summary

OCT 31 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Jul. 17, 2008

1. Company and Correspondent making the submission:

Name – E-WOO Technology Co., Ltd.

Address – 1F, 4F, Yunmin Technotown, 473-4, Bora-dong, Giheung-gu, Yongin-si, Gyeonggi-do, 449-904, Korea

Telephone – +82-31-285-6950

Fax – +82-31-286-3007

Contact – Mr. DongTaek, Oh

Internet – http://www.e-wootech.com

2. Device :

Trade/proprietary name	: Master3DS
Common Name	: X-ray, tomography, computed, dental
Classification Name	: X-ray, tomography, computed, dental

3. Predicate Device :

Manufacturer	: Imaging Sciences International, Inc.
Device	: i-CAT
510(k) Number	: K061284(Decision Date - Jul. 3. 2006)

4. Classifications Names & Citations :

21CFR 892.1750, OAS, X-ray, tomography, computed, dental, Class2

5. Description :

5.1 General

E-WOO Dental Imaging system Master3DS is a Computed Tomography X-ray

System. Computed Tomography (CT) provides valuable 3-D imaging of the dental and maxillofacial structures for diagnosis and treatment planning. Uses of CT imaging include for assessment of impacted teeth, root configurations and mandibular condyle evaluation. This technology allow for 3-D imaging but at lower equipment cost, simpler image acquisition and lower patient radiation dose.

Model Master3DS is diagnostic equipment which consists of panoramic dental x-ray system and computed tomography x-ray system. The panoramic dental x-ray is a system based on digital and computed tomography (CMOS CT Sensor to Capture 3D x-ray Computerized tomogram scanned image)

5.2 Product features

- Master3DS, the dental CT system with digital panoramic unit, provides the high quality digital image.
- It is not necessary to attach / detach the panoramic sensor when you capture CT images by Auto-Switching system.
- It is possible to capture Maxillary, mandible and whole arch by wider FOV (12 * 7).
- With Picasso-Trio it is not required to purchase a CT and a panoramic system each separately.
- It is helpful for treatments by viewing the invisible part with a 3-D CT images.
- The disk space for installation is no bigger than that of a general panoramic system.
- A clear Tomography image upto minimum 0.1mm at any directions
- Drastically reduce X-Ray expose dose comparing with medical CT in consideration of patient's safety
- You can set and control the Examination Program Mode with a console PC
- Support more accurate diagnosis imaging than LCD as well as voice announcement function for patients and staffs
- Master3DS supports the DICOM Format

5 Indication for use :

The Master3DS is a X-ray, tomography, computed, dental that provides 3D imaging of dental and maxillofacial for diagnosis and treatment planning.

6 Comparison with predicate device :

E-WOO Technology Co., Ltd., believes that the Master3DS is substantially equivalent to the i-CAT of Imaging Sciences International, Inc..

7 Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1, EN/IEC 60601-2-7, EN/IEC 60601-2-28, EN/IEC 60601-2-32 and EN/IEC 60601-2-44 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification E-WOO Technology Co., Ltd. concludes that The Master3DS is safe and effective and substantially equivalent to predicate devices as described herein.

10. E-WOO Technology Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2008

E-WOO Technology Co., Ltd.
% Mr. Vincent Lee
President
E-WOO Technology USA, Inc.
256 North Sam Houston Pkwy E. #115
HOUSTON TX 77060

Re: K082410
Trade/Device Name: X-ray, tomography, computed, dental/Master3DS
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: August 17, 2008
Received: August 21, 2008

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

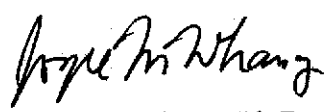
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K082410

Device Name: X-ray, tomography, computed, dental /Master3DS

Indications for Use:

The Master3DS is a X-ray, tomography, computed, dental that provides 3D imaging of dental and maxillofacial for diagnosis and treatment planning.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082410